

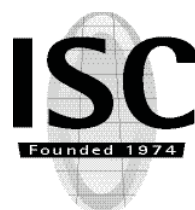
Prostate and Renal Cryoablation
CASE STUDY REVIEW

Briefing Series, Number 1

Publication 1003

Bilateral Renal Cryoablation Case

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International Society of Cryosurgery



Dear Reader,

The International Society of Cryosurgery is pleased to publish peer-reviewed case studies in urologic applications of cryosurgery.

In this issue Dr. Ibor Sawczuk reviews a bilateral renal cryoablation performed on patient Howard Pottruck. Dr. Sawczuk is Chairman of Urology and Chief of Urologic Oncology at Hackensack University Medical Center (Hackensack, New Jersey, USA); Professor of Surgery (in Urology) at University of Medicine and Dentistry of New Jersey (UMDNJ); and adjunct Professor of Urology at Columbia University.

We are grateful to Dr. Sawczuk for providing the case parameters, clinical discussion and images, with special thanks to Mr. Howard Pottruck for permitting publication of his story. In addition to adding an element of human interest, his account illustrates a subjective patient view of the advantages of renal cryoablation. Patients spend less time in the hospital and experience less pain than with partial nephrectomy procedures. There is potentially much less blood loss and no need to clamp the arterial blood supply to the kidney during the procedure.

We acknowledge Endocare, Inc. (Irvine, CA, USA) for sponsoring production of our series of cryoablation case studies.

Whether you are an experienced cryosurgeon, or a relative newcomer, I hope you find this case review to be of interest in managing renal cell carcinoma.

Sincerely,

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INTRODUCTION

Ihor S. Sawczuk, M.D. Presents A Renal Cryoablation Case

Cryoablation for the treatment of kidney lesions is gaining validation and popularity. At the 2005 American Urological Association conference (San Antonio, TX), 11 abstracts demonstrated growing interest and clinical exploration of renal cryoablation. At the 2004 AUA, two noteworthy studies revealed 4-year success rates of 95% and 92%, respectively. The ability to treat mid-pole lesions is an exciting aspect of renal cryo. Freezing into the collection system appears to have no negative impact on kidney function. Fistulas have not been observed as a result of freezing the tissue. There is far less potential blood loss and no need to clamp the arterial blood supply to the kidney during the procedure.

Ihor Sawczuk, M.D. presents a bilateral renal cryoablation case. Dr. Sawczuk received his Medical Degree from the Medical College of Pennsylvania. He completed his surgical internship and residency at St. Vincent's Hospital and Medical Center (New York City) followed by urological residency at Columbia Presbyterian Medical Center. Five years ago he became the Chairman of Urology and Chief of Urologic Oncology at Hackensack University Medical Center (Hackensack, New Jersey). He is currently a Professor of Surgery (in Urology) at UMDNJ New Jersey Medical School and an adjunct Professor of Urology at Columbia University.

Today most renal cancers are coincidentally detected during radiologic imaging for other conditions. Hence, they tend to be manageable in size. Dr. Sawczuk believes that renal cryoablation can be minimally problematic due to several facts: the anatomical location of the kidney within Gerota's fascia, the often abundant retroperitoneal fat, the relatively spherical nature of the renal tumors, and the multitude of the approaches to the kidney. Dr. Sawczuk's experience with over 40 renal cryoablations confirms previous published studies of the feasibility, safety and promising efficacy of this modality. This case coupled with patient Howard Pottruck's own story attest to the potential advantages for patients.

CASE STUDY

A Renal Case Study: Mr. Howard Pottruck

Patient History

1999 - Mr. Pottruck (age 67) was found to have a papillary renal carcinoma, for which he underwent a right partial nephrectomy. His renal function was successfully spared. He was followed over the years with surveillance imaging i.e., CT scans and MRIs.

Aug. 2004 - As a result of monitoring, Mr. Pottruck (age 71) was found to have an enlargement of a previously indeterminate lesion on his right kidney. Further evaluation revealed bilateral renal masses.

Treatment Decision and Rationale

Because he had bilateral disease, it was thought that it would best serve him to undergo cryoablation of the renal masses in order to accomplish two goals: 1) treat the disease, and 2) preserve as much renal function as possible because he was considered to be at risk for future development of tumors. Mr. Pottruck was in otherwise good health.

Treatment

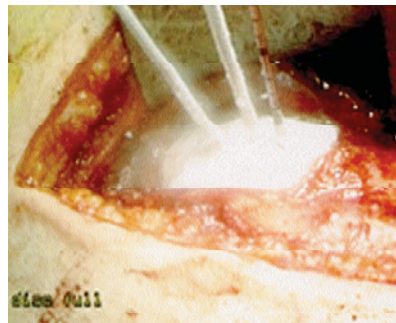
September 22, 2004 - Mr. Pottruck underwent a minimally invasive left laparoscopic renal cryoablation at Hackensack University Medical Center. The mass was biopsied prior to the ablation. The lesion measured 1.9 cm on the left posterior

upper pole: 2 percutaneous 17-gauge cryoprobes were placed into the mass under laparoscopic ultrasound guidance. Two standard freeze/thaw cycles were done, attaining a 1 cm margin around the mass. There were no complications.

November 10, 2004 - After several weeks' recuperation, Mr. Pottruck underwent an open cryosurgical ablation of the lesion on the right kidney. Laparoscopy would have been a difficult maneuver due to the previous partial nephrectomy.



Ultrasound image: initiation of freeze cycle with formation of ice-ball



Open laparoscopic approach showing probes and temperature monitor

Again, a biopsy was taken prior to ablation. The mass measured 2.1 cm along the lateral aspect. Two 17-gauge cryoprobes were placed directly into the mass. Two freeze/thaw cycles were administered, attaining a 1 cm margin. There were no complications.

Pathology

In each kidney the biopsy revealed renal cell carcinoma, papillary type, grade 2.

Recovery

Recovery was speedy and uneventful for both procedures. There were no clinical issues.

Follow-Up

January 18, 2006 - MRI scanning of the right side showed no masses, and revealed scar tissue formation in the kidney compatible with the previous cryoablation. Likewise, on the left side it also showed scar tissue formation compatible with cryoablation. Fourteen month follow-up has shown that Mr. Pottruck has remained cancer free.

Current Renal Function

Preoperatively, Mr. Pottruck's creatinine was 1.4 mg/dL. Postoperatively it has been maintained at 1.4 mg/dL (no change as a result of the bilateral cryoablation).

PHYSICIAN DIALOGUE

Dr. Sawczuk Reflects On His Experience

What do you find rewarding in your academic and clinical experience?

I enjoy teaching the medical students and residents. I like working with them to develop their knowledge and skills in basic urologic practice. As far as my clinical work, my philosophy is quite simple. Take care of the patient. Once you determine what the patient's urologic problem is, you offer the therapies that you think best serve the patient.

How did you become interested in cryoablation?

About five or six years ago I was performing surgery on difficult tumors within the kidney. My colleagues were also working at that time with cryosurgery of the prostate, and we looked at it and said perhaps we can use the cryosurgery for solid tumors in the kidney. We felt we would be able to ablate the tumor but at the same time maintain normal renal tissue and preserve renal function. At Hackensack University Medical Center I continued my work in cryoablation of renal cancers, especially those in solitary kidneys.

Did you follow the work of leaders in the field?

Yes, I was aware of leaders in the field who were using cryosurgery at that time in the kidneys, and we were following their written literature to see how we could adapt it, to see

what its pros and cons were, and to obtain our own clinical experience with it.

We did our first cases around 1999-2000, and had good success with them. The patients tolerated the procedure well, and we did not have any tumor recurrences in the patients that I did it on. From there, I continued using the modality in selected patients. I don't use it for all patients with kidney tumors, but in those patients who I think are candidates, I use cryoablation as a modality to treat their renal cancer.

Originally were you doing these as open cryosurgeries?

Initially they were open, and currently it depends on the location of the tumor in the kidney. Some patients are candidates for laparoscopic, but some are better suited for the open procedure due to the central location in the kidney or the difficulty of imaging the lesion. Some might even be candidates for percutaneous cryoablation, with radiologic imaging guidance.

How many renal cryos have you done?

Probably over 40, including a large number of patients with solitary kidneys.

Why did you elect cryoablation in Mr. Pottruck's case?

He was a person whom we had previously treated with partial nephrectomy of his right kidney,

and he was followed over the years with surveillance imaging. In August 2004 he was found to have recurrences in both of his kidneys. Rather than elect to remove his kidneys and put him on dialysis, we saw that his tumors were of the appropriate size and location for cryosurgical ablation and we elected to proceed with this form of definitive therapy.

Any other considerations in his medical history?

No, it was basically to maintain renal function and treat his tumors, because he was a high risk patient for recurrence.

Do you have a standard short and long-term follow up?

It depends on the pathology of the tumor, and on the procedure in terms of the cryoablation. I usually get MRI's afterwards to follow these lesions, and I tend to get the first imaging at about 4 months after the procedure, then every 6 months for 2 years, then once a year after that for an additional 3 years, and after that it depends on the clinical findings.

The ideas and opinions expressed herein are solely those of the interviewee.

PATIENT EXPERIENCE

My Kidney Cryo

By Mr. Howard Pottruck

I'm 72 and I'll be married 50 years in June, 2006. I have 2 daughters and 5 grandchildren. I'm self-employed and still working.

I was first diagnosed with kidney cancer 6 years ago, in my right kidney. My local urologist stated that I would probably have to remove it. My daughter, a nurse, made referrals that led to Dr. Sawczuk. He said, "There's no guarantee, but I'll try to save your kidney." He did a partial nephrectomy [partial surgical removal] and saved my kidney [function]. I then had annual CT scans. For about 5 years, I was cancer free with all normal functions and no medication.

Last year I was diagnosed again, with cancer in both kidneys. I knew something about cryosurgery. When I was 58 I had radiation for prostate cancer, but when it came back 10

years later, I had salvage cryo. So for my left kidney, Dr. Sawczuk first did a laparoscopic cryosurgery in Sept. 2004 at Hackensack University Medical Center. I had one night in the hospital, which is unbelievable, and no side effects. Then in November he did an open cryosurgery on my right kidney. I recovered so well that I went to Aruba two weeks later. I enjoyed a normal vacation.

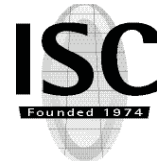
I have both of my kidneys. I'm not on dialysis. I play golf, do yard work, and I'm completely active. I have a positive outlook. As long as I know who I have to go to, and they can rectify it, I don't concern myself. I'm lucky that I found Dr. Sawczuk. He is a complete professional and a wonderful human being who cares for his patients.

For people who could have cryo, I'd say they'd be foolish

not to do it. Why go through something else? I had no internal bleeding, I didn't have anything. I just had my MRI and everything is good. People are afraid to try something new, but this is technology. That's what keeps you alive.

I was in California this past October, I played golf on the Olympic course. I shot from the blue tees and I shot 99. If I play there again, which I will, I'll break 90. What else can I tell you?

Patient experience provided courtesy of Howard Pottruck.



ISC Overview

The International Society of Cryosurgery (I.S.C.) was founded in 1974 to promote continuing medical education in the field of cryosurgery from an experimental and clinical point of view. The overall aim of the ISC is to continue to develop and expand membership of the society.

The headquarters of the Society are based in Casa di Cura Salus, Trieste, Italy. The Society corresponds with around 700 members worldwide. Membership is open to anyone who has a professional interest in research and education in the fields of Cryosurgery, Cryobiology, Cryopreservation, and other disciplines related to the use of low temperature in medicine.

ISC Activities:

To learn more please visit our website

<http://www.societyofcryosurgery.org/futMeetings/index.htm>

ISC Publication:

The Society produces a biannual publication 'Cryosurgery'

<http://www.societyofcryosurgery.org/publications/index/htm>, which covers all aspects of Cryosurgery and Cryobiology.

ISC Officers and Board Of Directors:

Please visit our website for a current listing:

<http://www.societyofcryosurgery.org/officers/index/htm>.

The case study presented here reflects the outcomes for a single physician and patient. Outcomes for other physicians and patients may vary so choice of treatment is best determined between a physician and patient where the risks can be evaluated specific to the individual patient. Cryoablation of the kidney, like all kidney procedures, involves certain risks including damage to renal function and/or the inability to save the kidney. Physicians and patients interested in cryoablation as a treatment for kidney cancer should familiarize themselves with the risks and long term outcomes as documented in recent published clinical data. For a bibliography of cryoablation published data please contact The International Society of Cryosurgery.

The Case Study Review is made possible by a grant from Endocare, Inc.



